



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned J. Dunston
Sheet	1	of	4	Attorney Docket Number	BSZ-050

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
JD	A1	4,078,052	03-07-1978	Papahadjopoulos	
	A2	4,698,327	10-06-1987	Nagarajan et al.	
	A3	4,725,442	02-16-1988	Haynes	
	A4	4 871 488	10-03-1989	Mannino et al.	
	A5	4,874,795	10-17-1989	Yesair	
	A6	4,906,476	03-06-1990	Radhakrishnan	
	A7	4 990 291	02-05-1991	Schoen et al.	
	A8	5,026,557	06-25-1991	Estis et al.	
	A9	5,100,591	03-31-1992	Leclef et al.	
	A10	5 269 979	12-14-1993	Fountain	
	A11	5,409,698	04-25-1995	Anderson et al.	
	A12	5,484,589	01-16-1996	Saiganik	
	A13	5,571,517	11-05-1996	Yesair	
	A14	5,580,859	12-03-1996	Feigner et al.	
	A15	5,589,466	12-31-1996	Feigner et al.	
	A16	5 643 574	07-01-1997	Gould - Fogerte et al.	
	A17	5,834,015	11-10-1998	Oleske et al.	
	A18	5,840,707	11-24-1998	Mannino et al.	
	A19	5,994,318	11-30-1999	Gould - Fogerte et al.	
	A20	6,420,754	11-10-2000	Unger Duplicate	
	A21	6,153,217	11-28-2000	Jin et al.	
	A22	6,340,591	01-22-2002	Margolis et al.	
	A23	6,403,056	06-11-2002	Unger	
	A24	6,406,713	06-18-2002	Janoff et al.	
↓	A25	6,447,800	09-10-2002	Hope	
	A26	6,592,894	07-15-2003	Zarif et al.	
JD	A27	6,808,720	10-26-2004	Unger	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number-Kind Code ⁴ (if known)			
JD	A28	FR 2 221 122 A	10-11-1974	Bayer AG	Abstract
	A29	EP 435 503 A1	07-03-1991	Eli Lilly and Co.	
	A30	EP 667 353 A1	08-16-1995	Eli Lilly and Co.	
	A31	WO 96 25942	08-29-1996	Albany Medical College et al.	
	A32	WO 97 30725	08-28-1997	Mannino et al.	
↓	A33	WO 00 42989	07-27-2000	Biodelivery Sciences, Inc. et al.	
	A34	WO 01 52817	07-26-2001	Biodelivery Sciences, Inc. et al.	
JD	A35	WO 04 012709	02-12-2004	Jin	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). ¹ See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ² Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Jennifer Dunston/ (06/29/2006)	Date Considered
--------------------	---------------------------------	-----------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449A/B/PTO				Complete If Known	
				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned J. Dunston
Sheet	2	of	4	Attorney Docket Number	BSZ-050

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
JD	B1	ANDERSON, et al. Formulation and evaluation of a folic acid receptor-targeted oral vancomycin liposomal dosage form. <i>Pharm Res</i> 18(3): 316-22, 2001.			
	B2	ARNDT, et al. Liposomal bleomycin: increased therapeutic activity and decreased pulmonary toxicity in mice. <i>Drug Deliv</i> 8(1): 1-7, 2001.			
	B3	ASAI, "Formation of the dispersed particles composed of retinol and phosphatidylserine," <i>Int J Pharm</i> , 253: 89-95, 2003.			
	B4	AVILES, et al. Pegylated liposomal doxorubicin in combination chemotherapy in the treatment of previously untreated aggressive diffuse large-B-cell lymphoma. <i>Med Oncol</i> 19(1): 55-58, 2002.			
	B5	BOOSER, et al. Anthracycline antibiotics in cancer therapy. Focus on drug resistance. <i>Drugs</i> . 47(2):223-58, 1994.			
	B6	COUVREUR, et al. Nano- and microparticles for the delivery of polypeptides and proteins. <i>Adv. Drug Delivery Rev</i> , 10: 141-162, 1993.			
	B7	CREUZENET, et al. Interaction of alpha s2- and beta-casein signal peptides with DMPC and DMPG liposomes. <i>Peptides</i> , 18(4): 463-472, 1997.			
	B8	DERES, et al. In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine. <i>Nature</i> . 342(6249):561-4, 1989.			
	B9	FINBERG, et al. The induction of virus-specific cytotoxic T lymphocytes with solubilized viral and membrane proteins. <i>J Exp Med</i> . 148(6):1620-7, 1978.			
	B10	GEMMELL, et al. Comparative effects of drugs on four paw oedema models in the rat. <i>Agents Actions</i> . 9(1): 107-116, 1979.			
	B11	GOODMAN-SNITKOFF, et al. The glycoprotein isolated from vesicular stomatitis virus is mitogenic for mouse B lymphocytes. <i>J Exp Med</i> 153: 1489-1502, 1981.			
	B12	GOODMAN-SNITKOFF, et al. Defining minimal requirements for antibody production to peptide antigens. <i>Vaccine</i> . 8(3):257-62, 1990.			
	B13	GOODMAN-SNITKOFF, et al. Role of intrastuctural/intermolecular help in immunization with peptide-phospholipid complexes. <i>J Immunol</i> . 147(2):410-5, 1991.			
	B14	GOULD-FOGERITE, et al. Chimerosome-mediated gene transfer in vitro and in vivo. <i>Gene</i> . 84(2):429-38, 1989.			
	B15	GOULD-FOGERITE, et al. Rotary dialysis: its application to the preparation of large liposomes and large proteoliposomes (protein-lipid vesicles) with high encapsulation efficiency and efficient reconstitution of membrane proteins. <i>Anal Biochem</i> . 148(1):15-25, 1985.			
	B16	GOULD-FOGERITE, et al. The reconstitution of biologically active glycoproteins into large liposomes: use as a delivery vehicle to animal cells. <i>Adv Membr Biochem Bioener</i> . 569-586, 1988.			
	B17	GOULD-FOGERITE, et al. Liposome preparation and related techniques. <i>Liposome Technology</i> , 2 nd Edition. 1:67-80, 1993.			
	B18	GOULD-FOGERITE, et al. Interaction of liposomes with the biological milieu. <i>Liposome Technology</i> , 2 nd Edition. 3:261-276, 1993.			
✓	B19	GOULD-FOGERITE, et al. "Mucosal and systemic immunization using cochleate and liposome vaccines" <i>J. Liposome Res</i> , 6(2): 357-79, 1996.			
JD	B20	GOULD-FOGERITE et al., "Targeting immune response induction with cochleate and liposome-based vaccines" <i>Adv Drug Delivery Rev</i> , 32(3), pgs. 273-287, 1998.			

Examiner Signature	/Jennifer Dunston/ (06/29/2006)	Date Considered
--------------------	---------------------------------	-----------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned, J. Dunston
Sheet	3	of	4	Attorney Docket Number	BSZ-050

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
JD	C1	GOULD-FOGERITE, et al. Cochleates for induction of mucosal and systemic immune responses. <i>Meth Molec Med</i> 42: 179-196, 1999.			
	C2	GOULD-FOGERITE, et al., Cochleate Delivery Vehicles: Applications in Vaccine Delivery. <i>J Liposome Res</i> , 10(4): 339-358, 2000.			
	C3	HALE, et al. Elicitation of anti-Sendai virus cytotoxic T lymphocytes by viral and H-2 antigens incorporated into the same lipid bilayer by membrane fusion and by reconstitution into liposomes. <i>J Immunol</i> . 124(2):724-31, 1980.			
	C4	JIN, U.S. Patent Application Publication No. 2004/0092727, published 05-10-2004. Duplicate			
	C5	LABELLE, et al. Improved methods for the delivery of liposome-sequestered RNA into eucaryotic cells. <i>Arch Biochem Biophys</i> . 215(2):486-97, 1982.			
	C6	LICHTENBERG, et al. Liposomes: Preparation, Characterization and Preservation. <i>Meth Biochem Anal</i> . 33:337-462, 1988.			
	C7	LONGENECKER, et al. Three dimensional structure of mammalian casein kinase I: Molecular basis for phosphate recognition. <i>J Mol Biol</i> , 257: 618-631, 1996.			
	C8	MANNINO, et al. Liposome mediated gene transfer. <i>Biotechniques</i> . 6(7):682-90, 1988.			
	C9	MANNINO, et al. Liposomes as adjuvants for peptides: Preparation and use of immunogenic peptide-phospholipid complexes. <i>Liposome Technology</i> , 2 nd Edition. 2:167-184, 1993.			
	C10	MANNINO, et al. Lipid matrix-based vaccines for mucosal and systemic immunization. <i>Pharm Biotechnol</i> . 6:363-87, 1995.			
	C11	MANNINO, et al. Antigen cochleate preparations for oral and systemic vaccinations. <i>New Gen Vaccines</i> 2 nd ed., Ch 18, pgs. 229-39, 1997.			
	C12	MILLER, et al. Vaccination of rhesus monkeys with synthetic peptide in a fusogenic proteoliposome elicits simian immunodeficiency virus-specific CD8+ cytotoxic T lymphocytes. <i>J Exp Med</i> . 176(6):1739-44, 1992.			
	C13	MORI, et al. Immunotargeting of liposomes containing lipophilic antitumor prodrugs. <i>Pharm Res</i> . 10(4):507-14, 1993.			
	C14	MORILLA, et al. Development and in vitro characterization of a benznidazole liposomal formulation. <i>Int J Pharm</i> 249(1-2): 89-99, 2002.			
	C15	OSOBA, et al. Effect of treatment on health-related quality of life in acquired immunodeficiency syndrome (AIDS)-related Kaposi's sarcoma: a randomized trial of pegylated-liposomal doxorubicin versus doxorubicin, bleomycin, and vincristine. <i>Cancer Invest</i> . 19(6): 573-80, 2001.			
	C16	PAPAHADJOPoulos, et al. Cochleate lipid cylinders formation by fusion of unilamellar vesicles. <i>Biochim Biophys Acta</i> . 394(3): 483-491, 1975.			
	C17	PAPAHADJOPoulos, et al. The use of lipid vesicles for introducing macromolecules into cells. <i>Prot Turnover Lysosome Funct</i> . 543-60, 1978.			
	C18	PARKER, et al. In vivo and in vitro antiproliferative effects of antisense interleukin 10 oligonucleotides. <i>Meth Enzym: Antisense Tech, Part B</i> 314: 411-29, 1999.			
↓	C19	SANDERSON, et al. Encapsulation of vancomycin and gentamycin with cationic liposomes for inhibition of growth of <i>Staphylococcus epidermidis</i> . <i>J Drug Target</i> 4(3): 181-89, 1996.			
JD	C20	SANTANGELO, et al. Efficacy of oral cochleate-amphotericin B in a mouse model of systemic candidiasis. <i>Antimicrob Agents Chemother</i> , pgs. 2356-2360, 2000.			

Examiner Signature	/Jennifer Dunston/ (06/29/2006)	Date Considered
--------------------	---------------------------------	-----------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				<i>Complete if Known</i>	
				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned
Sheet	4	of	4	Attorney Docket Number	BSZ-050

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
JD	D1	SUNDRAM, et al. General and efficient method for the solution- and solid-phase synthesis of vancomycin carboxamidine derivatives. <i>J Org Chem</i> 60:1102-03, 1995.			
	D2	WASSEF, et al. Liposomes as carriers for vaccines. <i>Immunomethods</i> . 4(3):217-22, 1994.			
	D3	ZARIF, et al., Amphotericin B cochleates as a novel oral delivery system for the treatment of fungal infection. <i>Proceedings of the International Symposium on Controlled Release of Bioactive Materials</i> , Illinois: Controlled Release Society, pgs. 964-965, 1999.			
	D4	ZARIF, et al. Antifungal activity of amphotericin B cochleates against <i>Candida albicans</i> infection in a mouse model. <i>Antimicrob Agents Chemother</i> 1463-1469, 2000.			
	D5	ZARIF, et al. Cochleates: New lipid based drug delivery system. <i>J. Liposome Res</i> 10(4): 523-538, 2000.			
↓	D6	Zarif, et al. Elongated supramolecular assemblies in drug delivery. <i>J. Controlled Rel</i> 81: 7-23, 2002.			
JD	D7	International Search Report for Application No. PCT/US2004/011026.			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Jennifer Dunston/ (06/29/2006)	Date Considered
--------------------	---------------------------------	-----------------